Congress of the United States
Washington, DC 20515

October 15, 2003

Mark B. McClellan
Commissioner
United States Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner McClellan,

We are writing to follow up on a letter sent by Massachusetts Attorney General Thomas Reilly concerning the importation of prescription drugs from Canada. We would like you to explain to us your current concerns about importing prescription drugs from Canada and to outline the steps you plan to take to establish a system that will ensure the safety and effectiveness of Canadian drug imports.

Over the next ten years, Americans over 65 will spend $1.8 trillion on prescription drugs. Some estimates indicate that importing prescription drugs from abroad could result in a 10 year saving of $630 billion. According to a recent study of U.S. and Canadian drug-price comparisons, on average, prices charged by manufacturers, wholesalers, and retailers were higher in the United States by about 70 percent. In light of the enormous impact of high drug prices on U.S. citizens, it is simply not sufficient to assert that pharmaceuticals imported from Canada may not be safe or effective without advancing a proposal that would resolve these concerns. Three years ago, in an effort to counter skyrocketing drug prices in the United States, Congress passed the Medicine Equity and Drug Safety Act, which permits the Food and Drug Administration to set up a system of drug imports from several countries, including Canada. We would like to know when we can expect you to establish such a system and what additional authority or resources are needed to make it work.

FDA's William Hubbard told the House Energy and Commerce Committee that consumers expose themselves to a number of potential risks when they purchase drugs from foreign sources. To respond to these concerns, you should establish a method of verifying the safety, efficacy, and security of Canadian drug imports or you should explain to us exactly why you believe this task cannot be achieved in a manner consistent with the public health.

As you may know, both Medicare reform bills, H.R 1 and S. 1, include prescription drug importation provisions with requirements for packaging, inspections, sample testing, chain-of-custody documentation, and registration of participants. To go even further to ensure safety, the FDA could also require anti-counterfeit technologies like those included in the House passed bill, H.R. 2427. We believe that there are reasonable steps that would provide the safeguards needed to allow for the safe

importation of medicines from Canada, especially because many of the drugs available in Canada are manufactured in the United States at the same facilities used to produce pharmaceuticals sold in the domestic market. If you have additional or alternative suggestions, we would like to know what they are.

We look forward to a quick response, so we can help you implement the importation of safe and effective drugs from Canada as quickly as possible.

Sincerely,

Edward Kennedy
United States Senator

John Kerry
United States Senator

Marty Meehan
Member of Congress

Edward Markey
Member of Congress

Barney Frank
Member of Congress

John Olver
Member of Congress

John Tierney
Member of Congress

James McGovern
Member of Congress

William Delahunt
Member of Congress

Stephen Lynch
Member of Congress

Richard Neal
Member of Congress